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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/084,587      | 02/25/2002  | Edward J. Gavin      | 016866-008200US     | 6008             |

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| EXAMINER |
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LAU, TUNG S

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| ART UNIT | PAPER NUMBER |
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2863

| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE  | DELIVERY MODE |
|--|------------|---------------|
| 3 MONTHS                               | 04/10/2007 | PAPER         |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

|                              |                               |                              |  |
|------------------------------|-------------------------------|------------------------------|--|
| <b>Office Action Summary</b> | Application No.<br>10/084,587 | Applicant(s)<br>GAVIN ET AL. |  |
|                              | Examiner<br>Tung S. Lau       | Art Unit<br>2863             |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 19 March 2007.  
 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.  
 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-40 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
 6) ☒ Claim(s) 1-40 is/are rejected.  
 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.  
 10) ☒ The drawing(s) filed on 02/25/2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) ☐ All b) ☐ Some \* c) ☐ None of:  
 1. ☐ Certified copies of the priority documents have been received.  
 2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>03/19/2007</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 03/19/2007 has been entered.

### **Information Disclosure Statement**

2. The information disclosure statement filed 03/19/2007 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because the date of the publication of the references is/are missing. It has been placed in the application file, but the information referred to therein has not been considered as to the merits (items AL, AP and AS). Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609 C(1).

***Claim Rejections - 35 USC § 101***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 101 that form the basis for the rejections under this section made in this Office action:

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-40 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

In claim 1, the method that analyzes mass spectra using a computer including entering data forming classification model. In claim 35, a computer readable medium including entering code derived from mass spectra, code for forming classification model. These claims appear to merely describe mathematical transformation and lack of concrete and tangible result. The practical application of the claimed invention cannot be realized until the information determined is conveyed to the user. For the result to be tangible it would need to output to a user or stored for later use. Hence the claims are treated as nonstatutory functional descriptive material (See MPEP § 2106 and OG Notices: 22 November 2005, Guidelines for Subject Matter Eligibility, <http://www.uspto.gov/web/offices/com/sol/og/2005/week47/patgupa.htm>

See MPEP 2106 IV B (1) (b).

For instance in claim 1, the method steps of entering data, forming classification model are data manipulation. This fails to present a concrete, tangible useful

result. An example of a concrete, tangible useful result may include displaying, storing for further use, generating a control signal etc. of the forming classification model.

For instance in claim 35, a computer readable medium including code for forming classification model. This fails to present a concrete, tangible useful result. An example of a concrete, tangible useful result may include displaying, storing for further use, generating a control signal etc. of the forming classification model.

The applicant should review the disclosure to determine what type of tangible result is being carried out in this instant application and such limitation be included in the claim. For further guidance see

<http://www.uspto.gov/web/offices/com/sol/og/2005/week47/patgupa.htm>

### **Double Patenting rejection**

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b). Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 1-34 and 39-40 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-100 of U.S. Patent No. 6,675,104 (copending application 09999081). Although the conflicting claims are not identical, they are not patentably distinct from each

other because the subject matter claimed in the instant application is fully disclosed in the previous application.

| Claim 1 (10/084,587)  | Claim 1, 2 (U.S. Patent 6,675,104)   |
|---|--|
| <p>1. A method that analyzes mass spectra using a digital computer, the method comprising:</p> <p>a) entering into a digital computer a data set obtained from mass spectra from a plurality of samples, wherein each sample is, or is to be assigned to a class within a class set comprising two or more classes, each class characterized by a different biological status, and wherein each mass spectrum comprises data representing signal strength as a function of time-of-flight, mass-to-charge ratio, or a value derived from time-of-flight or mass-to-charge ratio, and <u>is created using a laser desorption ionization process</u>; and</p> <p>b) forming a classification model which discriminates between the classes in the class set, wherein forming comprises analyzing the data set by executing code that embodies a classification process.</p> | <p>1. A method that analyzes mass spectra using a digital computer, the method comprising:</p> <p>a) entering into the digital computer a data set obtained from mass spectra from a plurality of samples, wherein each sample is, or is to be assigned to a class within a class set comprising two or more classes, each class characterized by a different biological status, and wherein each mass spectrum comprises data representing signal strength as a function of time-of-flight, mass-to-charge ratio, or a value derived from time-of-flight or mass-to-charge ratio; and</p> <p>b) forming a classification model which discriminates between the classes in the class set, wherein forming comprises analyzing the data set by executing code that embodies a classification process comprising a recursive partitioning process, which is a classification and regression tree process.</p> <p>2. The method of claim 1 wherein the mass spectra are selected from the group consisting of MALDI spectra, surface enhanced laser desorption/ionization</p> |

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|  | spectra, and electrospray ionization spectra. |
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***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-40 are rejected under 35 U.S.C. 102(e) as being anticipated by Hitt et al. (U.S. Patent application Publication 2003/0004402).

**Regarding claim 1:**

Hitt describes a method that analyzes mass spectra (page 3, section 0019) using a digital computer (page 3, section 0023), the method comprising: a) entering into a digital computer a data set obtained from mass spectra from a plurality of samples (page 2, section 0016), wherein each sample is, or is to be assigned to a class within a class set comprising two or more classes (page 3, section 0021), each class characterized by a different biological status (page 2, section 0021), and wherein each mass spectrum comprises data representing signal strength as a function of time-of-flight (page 4, section 0032), mass-to-charge ratio, or a value derived from time-of-flight or mass-to-charge ratio using laser ionization

desorption process (page 4, section 0032); and b) forming a classification model which discriminates between the classes in the class set (page 4, section 0032), wherein forming comprises analyzing the data set by executing code that embodies a classification process comprising a recursive partitioning process (page 4, section 0032).

**Regarding claim 35:**

Hitt describes a computer readable medium (page 3, section 0023) a) code for entering data set obtained from mass spectra (page 3, section 0019) from a plurality of samples (page 2, section 0016), wherein each sample is, or is to be assigned to a class within a class set comprising two or more classes (page 3, section 0021), each class characterized by a different biological status (page 3, section 0021), and wherein each mass spectrum comprises data representing signal strength as a function of time-of-flight (page 4, section 0032), mass-to-charge ratio, or a value derived from time-of-flight or mass-to-charge ratio using laser ionization desorption process (page 4, section 0032); and b) forming a classification model which discriminates between the classes in the class set (page 4, section 0032), wherein forming comprises analyzing the data set by executing code that embodies a classification process comprising a recursive partitioning process (page 4, section 0032).



**Regarding claim 2**, Hitt further describes the mass spectra are selected from the group consisting of MALDI spectra (page 4, section 0032), surface enhanced laser desorption/ionization spectra, and electrospray ionization spectra.

**Regarding claim 3**, Hitt further describes the class set consists of exactly two classes (page 1, section 0003)

**Regarding claim 4**, Hitt further describes samples comprise biomolecules selected from the group consisting of polypeptides and nucleic acids (page 3, section 0019).

**Regarding claim 5**, Hitt further describes the samples are derived from a eukaryote, a prokaryote or a virus (abstract).

**Regarding claim 6**, Hitt further describes a normal status (page 1, section 0007) and a pathological status (abstract).

**Regarding claim 7**, Hitt further describes un-diseased (page 1, section 0007), low grade cancer and high grade cancer (page 1, section 0005).

**Regarding claim 8**, Hitt further describes comprise a drug-responder state and a drug-non-responder state (page 8, section 00077, medical condition of any state).

**Regarding claim 9**, Hitt further describes comprise a drug-responder state and a drug-non-responder state (page 8, section 00077, medical condition of any state).

**Regarding claim 10**, Hitt further describes comprise a toxic state and a non-toxic state (page 8, section 00077, medical condition of any state).

**Regarding claim 11**, Hitt further describes exposure to drug (page 9, section 0082).

**Regarding claim 12**, Hitt further describes the data set is a known data set (page 1, section 0008), and each sample is assigned to one of the classes before the data set is entered into the digital computer (page 3, section 0017).

**Regarding claim 13**, Hitt further describes forming the classification model comprises using pre-existing marker data to form the classification model (page 3, section 0024).

**Regarding claim 14**, Hitt further describes data representing signal strength as a function of mass-to-charge ratio (page 1, section 0006); clustering the signals having similar mass-to-charge ratios into signal clusters (page 1, section 0006); selecting signal clusters having at least a predetermined number of signals with signal intensities above a predetermined value (page 1, section 0006); identifying the mass-to-charge ratios corresponding to the selected signal clusters (page 1, section 0006); and forming the data set using signal intensities at the identified mass-to-charge ratios (page 1, section 0006).

**Regarding claim 15**, Hitt further describes at least one of identifying features that discriminate between the different biological statuses, and learning (page 3, section 0018).

**Regarding claims 16, 36**, Hitt further describes neural network analysis (page 4, section 0026).

**Regarding claim 17**, Hitt further describes interrogating the classification model to determine if one or more features discriminate between the different biological statuses (page 6, section 0059).

**Regarding claim 18**, Hitt further describes repeating and using a larger plurality of samples (page 7, section 0062).

**Regarding claim 19**, Hitt further describes cluster analysis (page 7, section 0064).

**Regarding claim 20**, Hitt further describes forming the data set, wherein forming the data set comprises obtaining raw data from the mass spectra (page 7, section 60) and then preprocessing the raw mass spectra data to form the data set (page 7, section 60).

**Regarding claim 21**, Hitt further describes the different classes are selected from exposure to a drug, exposure to one of a class of drugs and lack of exposure to a drug or one of a class of drugs (page 1, section 0005).

**Regarding claim 21**, Hitt further describes value derive from mass-charge-ratio (page 2, section 0016).

**Regarding claim 22**, Hitt further describes representing signal strength as a function mass-to-charge ratio or a value derived from mass-to-charge ratio (page 2, section 0016).

**Regarding claims 23, 28**, Hitt further describes entering data obtained from a mass spectrum of the unknown sample into a digital computer; and processing

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the mass spectrum data using the classification model formed by the method (page 2, section 0015).

**Regarding claim 24**, Hitt further describes comprise un-diseased, low grade cancer and high grade cancer (page, 1, section 0005).

**Regarding claim 25**, Hitt further describes to a drug of one of a class of drugs (page 8, section 00077, medical condition of any state).

**Regarding claim 26**, Hitt further describes response to a drug (page 8, section 00077, medical condition of any state).

**Regarding claim 27**, Hitt further describes toxicity status (page 8, section 00077, medical condition of any state).

**Regarding claims 29, 32**, Hitt further describes code for entering data obtained from a mass spectrum of an unknown sample into a digital computer; and code for processing the mass spectrum data using the classification model formed by the method to classify the unknown sample in a class characterized by a biological status (page 2, section 0015).

**Regarding claims 30, 33, 37**, Hitt further describes a gas phase ion spectrometer (page 1, section 0003); a digital computer adapted to process data from the gas phase ion spectrometer; and the computer readable medium in operative association with the digital computer (page 3, section 0023).

**Regarding claims 31, 34, 38**, Hitt further describes adapted to perform a laser desorption ionization process (page 4, section 0032).

**Regarding claims 39**, Hitt further describes material is antibodies (page 6, section 0059).

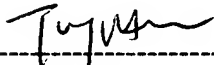
**Regarding claims 40**, Hitt further describes entering data obtained from a mass spectrum of the unknown sample into a digital computer (page 3, section 0023), wherein the mass spectrum is derived from a surface enhanced laser desorption/ionization process (page 4, section 0032) using a substrate comprising an affinity material, wherein the affinity material comprises antibodies (page 6, section 0059); and processing the mass spectrum data using the classification model formed by the method to classify the unknown sample in a class characterized by a biological status (page 3, section 0021).

### ***Response to Arguments***

6. Applicant's arguments filed 03/19/2007 have been fully considered and they are not persuasive.
7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tung S Lau whose telephone number is 571-272-2274. The examiner can normally be reached on M-F 9-5:30. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John Barlow can be reached on 571-272-2269. The fax phone numbers for the organization where this application or proceeding is assigned is 703-872-9306

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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Tung S. Lau  
AU 2863, Patent examiner  
April 3, 2007